REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Attached hereto is a substitute specification as Exhibits A and B. Exhibit A is the substitute specification with markings to show all the changes relative to the immediate prior version. Exhibit B is a clean version of the substitute specification.

The herein amendments to the specification address the objection to the specification.

No new matter is added.

Claims 1-20 are currently under consideration. Claims 1 and 6-12 are amended, claim 4 is cancelled, and claims 13-20 are newly added without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled.

The amendment to claims 1 and 6-8 relates to italicizing the term, *Aloe vera*. The amendment to claims 9-12 relates to clarifying the embodiments of the invention. Support for new claims 13-20 can be found, for example, on page 3, beginning on the fifth paragraph, and in the claims as originally filed.

II. OBJECTION OF THE SPECIFICATION IS OVERCOME

The specification was objected because the specification does not contain an abstract of the disclosure as required by 37 C.F.R. § 1.72(b). In response, Applicants amend the specification to contain an abstract of the disclosure.

The specification was also objected because the specification did not recite generic terminology with each trademark. In response, Applicants amend the specification to recite "polyacrylate adhesive" and "acrylate-vinyl acetate" with each recitation of Durotak 2287 and Durotak 2516, respectively. .

Applicants also note that the specification is amended to the format pursuant to 37 C.F.R. § 1.77(b).

Accordingly, reconsideration and withdrawal of the objection to the specification are respectfully requested.

III. REJECTION UNDER 35 U.S.C. § 112, 2ND PARAGRAPH IS OVERCOME

Claims 4 and 9-12 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. This rejection is respectfully traversed.

The Office Action alleges that the scope of claim 4 is uncertain since the trademarks Durotak 2287 and Durotak 2516 are used as a limitation, and a trademark cannot be used to identify any particular material or product in claims. Claim 4 is herein cancelled, thereby obviating the rejection against this claim.

The Office Action also contends that the terms "preferably" and "especially" in claims 9-12 are indefinite and may be subjected to more than one interpretation. Claims 9-12 are amended herein, and claims 13-20 are newly added in order to clarify the matrix without the recitation of the terms "preferably" or "especially."

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph are respectfully requested.

IV. REJECTIONS UNDER 35 U.S.C. §103(a) ARE OVERCOME

Claims 1-12 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 93/23025 (hereinafter " WO '025") in view of Japanese Patent No. 61-129117 (hereinafter "JP '117") and U.S. Patent No. 6,198,017 (hereinafter "US '017"). The rejection is respectfully traversed.

According to the Office Action, WO '025 relates to a transdermal patch for delivering oxybutynin comprising an adhesive matrix of the drug and a permeation enhancer. The Office

Action contends that the *Aloe vera*-extract mentioned in JP '117 can replace the permeation enhancer of WO '025 in order to increase permeability, and the adhesive polymer matrix of US '017 can be used to improve adherence.

The issue under §103 is whether the PTO has stated a case of prima facie obviousness. "The PTO has the burden under §103 to establish a prima facie case of obviousness." In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To satisfy this burden, the PTO must meet the criteria set out in M.P.E.P. §706.02(j):

> ...three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

In consideration of the above background, Applicants contend that the Patent Office has failed to meet its burden of making a prima facie case of obviousness. The Office has failed to demonstrate how the references provide sufficient teachings or motivation to be combined with knowledge available to one skilled in the art, or with each other, in order to arrive at the claimed invention. Further, the Patent Office has failed to show that there is a reasonable expectation of success that the combination of the references will arrive at the claimed invention.

Firstly, one skilled in the art would not be motivated to combine the teachings of these cited references. WO '025 indicates that the behavior of permeation enhancers is "highly idiosyncratic" and that a permeation enhancer "effective for one drug may not be effective with other drugs, including closely related drugs" (page 5, lines 26-29). WO '025 further mentions that many enhancers "interact adversely with other components of transdermal devices" and can cause "compatibility problems throughout the delivery system" (page 5, line 30 - page 6, line 16). Therefore, in light of the difficulties associated with combining permeation enhancers with transdermal patches, as well as the compatibility issues between permeation enhancers and drugs, a skilled artisan would not be motivated to combine the transdermal patch of WO '025 and the permeation enhancer of JP '117. In fact, WO '025 teaches away from combining transdermal patches of WO '025 with permeation enhancers that are not specified in the WO

'025 reference. With this in consideration, one skilled in the art would not be motivated to combine the cited references.

Furthermore, a skilled artisan would not reasonably expect that the transdermal patch of WO '025 and the permeation enhancer, i.e., *Aloe vera*, of JP '117 can be successfully combined. In view of the difficulties associated with finding compatible and effective permeation enhancers for transdermal patches (page 5, lines 26-29; page 5, line 30 - page 6, line 16), a skilled artisan would not expect that other permeation enhancers aside from those disclosed in WO '025 could be successfully combined with the transdermal patch of WO '025. Therefore, given the known difficulty in combining transdermal patches and permeation enhancers, a skilled artisan would not reasonably expect to successfully arrive at the present invention by combining WO '025 and JP '117.

Claims 1-12 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,601,839 (hereinafter "US '839") and in further view of JP '117 and US '017. The Office Action contends that US '839 relates to a transdermal device for delivering oxybutynin comprising an adhesive matrix with the drug and a permeation enhancer. One skilled in the art would allegedly be motivated to replace the permeation enhancer with *Aloe vera*-extract mentioned in JP '117 to increase permeability, and to additionally use the adhesive polymer matrix of US '017 to improve adherence. This rejection is respectfully traversed.

To reiterate the arguments above, it is known in the art that the behavior of permeation enhancers is highly idiosyncratic and that permeation enhancers are not universally compatible with all drugs, even closely related drugs. Further, many enhancers interact adversely with other components of transdermal devices. One skilled in the art would not be motivated to combine the transdermal patch of US '839 with the permeation enhancer of JP '117 in view of the known compatibility issues of permeation enhancers and transdermal patches. A skilled artisan would also not expect that the transdermal patch of US '839 can be successfully combined with the permeation enhancer of JP '117, given the idiosyncratic nature of permeation enhancers and their uncertain compatibility with drugs.

As such, the Office Action has failed to meet its burden of making a prima facie case of obviousness. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

V. OBJECTION TO THE CLAIMS ARE OVERCOME

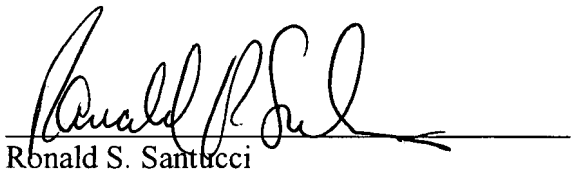
Claims 1-12 were objected because the plant species *Aloe vera* should be italicized. In response, Applicants amend claims 1, 6-8, and 10 to italicize *Aloe vera*. Accordingly, reconsideration and withdrawal of the objection to the claims are respectfully requested.

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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